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The M-Heart Percutaneous Balloon Mitral Valvuloplasty Registry: Initial Results and Early Follow-Up

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The initial results, complications and early follow-up of 74 patients undergoing percutaneous balloon mitral valvuloplasty in seven hospitals participating in a multicenter registry are reported. Seventy-four patients with a mean age of 53 years had 75 valvuloplasty procedures performed over a 2.5 year period. Eighty-nine percent of the attempted procedures were completed and resulted in an increase in mean mitral valve area from 1.0 ± 0.04 to 2.0 ± 0.1 cm^2 ($p < 0.0001$); the valve area increased ≥50% of the baseline valve area in 73% of the patients.

Major complications included procedure-related death (2.7%), cardiac tamponade (6.7%), systemic embolism (2.7%) and emergency surgery (6.7%). At a mean follow-up period of 14.6 months, the condition of the majority of patients had improved, and 89% of 55 patients treated only with valvuloplasty were in New York Heart Association functional class I or II.

Thus, hemodynamic and clinical improvement can be obtained in the majority of patients with mitral stenosis treated with balloon valvuloplasty in multiple centers. However, suboptimal results and major complications occurred in a significant number of patients and may limit this procedure to use by experienced operators in hospitals with facilities for cardiac surgery.

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Percutaneous balloon mitral valvuloplasty has emerged as a successful alternative to surgical commissurotomy in many patients with mitral stenosis (1–3). Since the first descriptions of this procedure by Inoue et al. (4) and Lock et al. (5), several improvements in its application have been made. First, the finding that a single balloon up to 25 mm in diameter is not large enough to fully dilate most adult valves (6,7) has led to the use of the double balloon technique (8) and, more recently, to the use of larger single balloons (9). Second, patient selection for a valve with the most mobility and the least thickening, calcification and subvalvular disease has improved both the immediate hemodynamic results of valvuloplasty (6,10,11) and the outcome during short-term follow-up (12). Finally, good results have also been obtained in patients after prior commissurotomy (13) and in those with a stenotic bioprosthetic valve (14).

Most reports (1–3) to date from single centers with a large volume and extensive experience have demonstrated good initial results and low complication rates. In this report, we review the experience with mitral valvuloplasty collected in the multicenter M-Heart Valvuloplasty Registry, with particular emphasis on early patient outcome and the technical problems and complications encountered by multiple operators.

Methods

Study patients. The study group consisted of 74 patients undergoing 75 attempted valvuloplasty procedures from May 1986 to January 1989 in seven hospitals (listed in the Appendix). The M-Heart Valvuloplasty Registry was formed in November 1987; data were collected retrospectively for procedures before this date (24%) and prospectively thereafter. Baseline clinical information and hemodynamic results were recorded on a standardized form and forwarded to a

*A list of the participating hospitals and investigators in the M-Heart Balloon Valvuloplasty Registry is presented in the Appendix.

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central data analysis center. The number of patients studied in each center was as follows (center number corresponds to the listing in the Appendix): center 1, 23; center 2, 15; center 3, 8; center 4, 8; center 5, 2; center 6, 8; and center 7, 10. Informed consent was obtained as required by each center's institutional review board.

Valvuloplasty procedure. The valvuloplasty procedure used in all centers was similar to the procedure initially described by Lock et al. (5). However, in the majority of procedures, the double balloon technique as modified to utilize a single atrial septostomy was used (1,8). All patients systemically received heparin during the procedure. The frequency of use of the combination of largest balloon diameters for each of the 67 completed procedures was as follows: 20 mm + 20 mm in 25; 18 mm + 18 mm in 5; 15 mm + 23 mm in 1; 18 mm + 20 mm in 7; 15 mm + 20 mm in 5; 15 mm + 18 mm in 2; and 15 mm + 15 mm in 1. The largest diameter single balloon used in the remaining procedures was 30 mm in 9; 25 mm in 3; 23 mm in 2; 20 mm in 6; and 15 mm in 1. For the purposes of comparison, the effective balloon dilating area (EBDA, in cm^2) in double balloon procedures was calculated as the sum of the area of two half circles and the trapezoidal region subtending them using the formula $EBDA = \pi/2\,(a^2 + b^2) + (a + b)^2$, where a and b are the radii of the balloons. The amount of shunting through the artificially created atrial septal defect was calculated using standard formulas, and a mixed venous oxygen content was calculated as 3/4 × superior vena cava oxygen content + 1/4 × inferior vena cava oxygen content.

Follow-up. Patients were contacted by telephone during July 1989 by a single research nurse at the coordinating center. Information on clinical events after hospital discharge, rehospitalization, New York Heart Association functional class and the patient's subjective assessment of functional improvement was ascertained. The rate of restenosis was assessed clinically and included patients who developed recurrent symptoms or died during the follow-up period; patients who died of noncardiac causes and those with a large (≥3 angiographic grades) increase in mitral regurgitation were excluded from this category.

Statistics. All results are expressed as mean values ± SEM. Hemodynamic and functional data were compared before and after valvuloplasty using analysis of variance with repeated measures (Newman-Keuls), and differences were considered significant if the p value was <0.05.

Results

Baseline clinical characteristics. The study group consisted of 65 women and 9 men, with a mean age of 53 ± 2 years (range 14 to 92). All patients had symptoms of heart failure: 17 patients were in functional class II, 45 were in class III and 12 were in class IV. The baseline mean transmitral gradient was 15 ± 1 mm Hg, and the mean cardiac output was 4.2 ± 0.1 liters/min, yielding a calculated mean mitral valve area of 1.0 ± 0.04 cm^2 before valvuloplasty. The mean pulmonary artery pressure was 36 ± 2 mm Hg, mean left atrial pressure was 26 ± 1 mm Hg and pulmonary vascular resistance was 221 ± 29 dyne·s·cm^{-5}.

Table 1. Initial Hemodynamic Results of Mitral Valvuloplasty in 67 Completed Procedures

	Before	After	p Value
Transmitral gradient (mm Hg)	15 ± 1	7 ± 1	<0.0001
Cardiac output (liters/min)	4.2 ± 0.1	4.8 ± 0.2	<0.001
Mitral valve area (cm^2)	1.0 ± 0.04	2.0 ± 0.1	<0.0001
Left atrial pressure (mm Hg)	26 ± 1	17 ± 1	<0.001
Pulmonary artery pressure (mm Hg)	36 ± 2	31 ± 2	<0.001
Pulmonary vascular resistance (dyne·s·cm^{-5})	221 ± 29	237 ± 30	NS

Hemodynamic effects of valvuloplasty (Table 1). Percutaneous balloon mitral valvuloplasty was attempted 75 times in the 74 patients (1 patient had repeat valvuloplasty for restenosis). The procedure was completed 67 times in 66 patients, for a completion rate of 89%. The mean valve gradient decreased from 15 ± 1 to 7 ± 1 mm Hg ($p < 0.0001$) and mean mitral valve area increased from 1.0 ± 0.04 cm^2 (range 0.5 to 1.7) to 2.0 ± 0.1 cm^2 (range 0.8 to 4.9) ($p < 0.0001$). Cardiac output increased, mean left atrial and pulmonary artery pressures decreased and pulmonary vascular resistance was unchanged.

The procedure was considered technically successful if mitral valve area increased by ≥50%; this increase occurred in 54 patients (55 [73%] of 75 attempts). The valvuloplasty procedure was terminated before completion in eight patients: left ventricular perforation occurred in four patients during balloon inflation or positioning; two procedures were aborted after a systemic embolism; one patient developed hypotension and arrhythmia before balloon inflation; and the balloon was never inserted in one patient in whom satisfactory wire position was not attained. In an additional 12 patients, the procedure was judged unsuccessful based on a suboptimal hemodynamic result defined as <50% increase in mitral valve area due to either a complication (3 patients), technical difficulties (3 patients) or an unknown cause (6 patients). Although patients with a suboptimal result tended to have a smaller mean effective balloon dilating size, this difference was not statistically significant.

Table 2. Major Complications in 75 Procedures

	No.
Left ventricular perforation and subsequent death	2
Cardiac perforation (tamponade)	5
Cardiac arrest	1
Systemic embolism	2
Mitral regurgitation (increase ≥2 grades)	6

Complications (Table 2). Sixteen major complications occurred in 15 patients: left ventricular perforation and subsequent death (n = 2), cardiac tamponade (n = 5), cardiac arrest (n = 1), systemic embolism to the central nervous system (n = 1) or the right coronary artery (n = 1) and increase in mitral regurgitation of ≥2 grades (n = 6). Additional minor complications included electrocardiographic conduction abnormalities persisting for >24 h (n = 4), bleeding or hematoma formation requiring blood transfusion (n = 5), venous thrombosis (n = 1), hypotension during balloon inflation causing transient neurologic symptoms (n = 3), arrhythmia requiring cardioversion (n = 1), benign cardiac perforation (n = 2) and possible embolic events without sequelae (n = 3).

Two patients died as a result of valvuloplasty (mortality rate 2.7%). In one patient, left ventricular apical rupture occurred during inflation of two 3 cm long 18 mm diameter balloons over guide wires positioned in the descending aorta, and the patient died after emergency surgery. The second patient also suffered from a perforation at an unknown point during the procedure, developed cardiac arrest after pericardiocentesis and died 3 days after emergency surgery. Cardiac perforation due to complications of the transseptal procedure or inadvertent perforation by a wire occurred in nine patients. In two patients, perforation resulted in pericarditis, but there were no hemodynamic changes. However, cardiac tamponade occurred in seven patients, requiring pericardiocentesis (three patients) or surgery (four patients including the two deaths described earlier). The total emergency surgery rate was 6.7% (five patients).

Left ventriculography was performed both before and after valvuloplasty in 48 patients. The degree of mitral regurgitation was unchanged or improved in 33 patients (69%), increased by 1 grade in 9 patients (19%) and increased by ≥2 grades in 6 patients (13%). Although mean effective balloon dilating area was higher in patients who developed regurgitation (4.05 ± 0.13 versus 3.54 ± 0.14 cm^2/m^2, p = 0.03), the range of balloon sizes was wide and the occurrence of mitral regurgitation could not be predicted on the basis of balloon size alone (r = 0.17, p = NS) (Fig. 1). Finally, the size of the left to right shunt through the iatrogenically created atrial septal defect was calculated in 45 patients and revealed a pulmonary to systemic flow ratio ≥1.3 in eight patients (18%); the average shunt ratio was 1.4 ± 0.1 (range 1.3 to 1.9).

Follow-up (Fig. 2 and 3). The procedure was not completed in eight patients, resulting in death (two patients) or mitral valve replacement (four patients) before hospital discharge. Three additional patients underwent early mitral valve replacement for suboptimal valvuloplasty results. The outcome in the remaining 63 patients was evaluated at a mean of 14.6 ± 0.9 months after valvuloplasty.

Ten patients (16%) had clinical evidence of restenosis: one patient underwent repeat dilation; four had mitral valve surgery for restenosis (one had surgery for severe regurgitation and was not classified as having restenosis); four symptomatic patients are awaiting further treatment and one died from cardiac causes during the follow-up period. With multiple linear regression analysis, the occurrence of restenosis could not be predicted by patient age, functional class, initial or final valve gradient and valve area, the change in valve area or balloon size used during the procedure. Among the 15 patients with an increase in regurgitation, 4 patients required mitral valve replacement, but in only 1 did the cause appear to be mitral regurgitation, and a 92 year old women who was not a surgical candidate died of progressive heart failure 6 weeks after valvuloplasty. The remaining 10 patients had clinical improvement despite an increase in regurgitation.

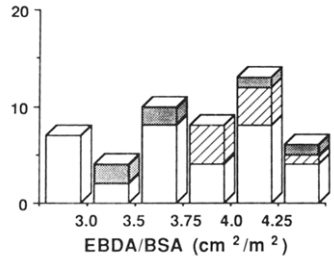


Figure 1. Effect of balloon valvuloplasty on the development of mitral regurgitation in 48 patients who underwent left ventriculography before and after the procedure. The angiographic grade of regurgitation increased by ≥2 grades in 13% (**shaded bars**), and by 1 grade in 19% (**hatched bars**) and was unchanged in 69% (**open bars**). There was no significant correlation (r = 0.17, p = NS) between effective balloon dilating area normalized for body surface area (EBDA/BSA) and the change in grade of mitral regurgitation.

Most patients (including the patient undergoing repeat dilation) had clinical improvement, with an overall follow-up technical success rate for valvuloplasty of 69% (51 of 74 patients) (Fig. 2). At follow-up evaluation, 49 (89%) of the 55 patients treated only by valvuloplasty were in functional class I or II, and no patient had class IV symptoms (Fig. 3); mean functional class improved from 2.9 ± 0.1 to 1.4 ± 0.1 (p < 0.0001).

Discussion

Reports from several institutions (1–3,15–17) have documented the beneficial effects of percutaneous balloon mitral valvuloplasty for the relief of symptoms in adult patients with acquired mitral stenosis. In this report, we extend these observations to the results of this procedure from a multihospital registry, in which each operator has less individual experience. The immediate hemodynamic results of valvuloplasty for hospitals in the registry were the same as those reported from single centers; transmitral gradient decreased by approximately 50%, and mitral valve area increased by 100% from 1 to 2 cm^2.

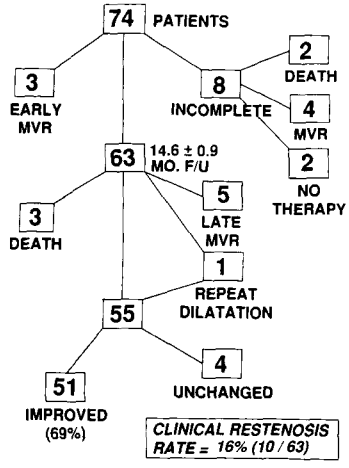
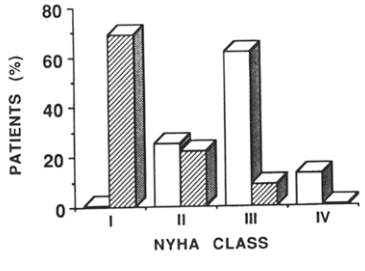


Figure 2. Outcome of all 74 patients included in the M-Heart Balloon Mitral Valvuloplasty Registry. Excluding eight procedures that were not completed and 3 patients who had early mitral valve replacement (MVR) for suboptimal hemodynamic results, 63 patients underwent follow-up (F/U) evaluation at a mean of 14.6 ± 0.9 months (MO.) after valvuloplasty. Sixty-nine percent of all patients had clinical improvement as a result of valvuloplasty, and 16% had no change in condition or experienced recurrent symptoms.

Clinical success rate. A technically successful procedure (defined as a completed procedure resulting in ≥50% increase in valve area) was obtained in 73% of attempted procedures, with a suboptimal hemodynamic result occurring in 16% of the procedures. This success rate was the same as that obtained in the initial Massachusetts General Hospital experience (6) when the same definition of success is applied. This arbitrary definition of success was chosen so as not to exclude patients with a severely stenosed valve (for example, valve area <0.7 cm^2) in whom the final result might not have exceeded a given final valve area, but in whom we observed clinical improvement. In this regard, there were no significant differences in success rate or percent change in any hemodynamic variable or functional class in patients with an initial mitral valve area <1 cm^2 (n = 36) as compared with patients with an initial mitral valve area ≥1 cm^2 (n = 34). If it can be demonstrated that long-term clinical improvement correlates better with the final valve area than with the percent increase in area, a definition for procedural success that incorporates final mitral valve area may be more useful.

Figure 3. Percent of patients in each New York Heart Association (NYHA) functional class before (**open bars**) and after (**hatched bars**) valvuloplasty among the 55 patients treated only with this procedure. Mean functional class improved from 2.9 ± 0.1 to 1.4 ± 0.1 ($p < 0.0001$).



Other studies (10,11) have demonstrated that the immediate hemodynamic results of valvuloplasty depend in part on morphologic characteristics of the valve, which can be assessed echocardiographically. Echocardiographic score was not recorded in all registry hospitals, and patient selection was performed at the discretion of the individual investigators. It is important to note that all patients undergoing valvuloplasty at each center were entered in the registry, many before the utility of echocardiographic selection of suitable candidates was widely appreciated.

Finally, a variety of alternative methods for performance of balloon valvuloplasty have now been described (18,19). All patients in this registry underwent anterograde valvuloplasty utilizing single or double balloons. There was a weak correlation between balloon size and a suboptimal hemodynamic result as previously described (6), but most of these suboptimal hemodynamic results occurred with a single balloon ≤25 mm in diameter.

Complications. The rate of most major complications was similar to that reported by single centers with extensive experience (3,20,21) and that in a preliminary report of the National Heart, Lung, and Blood Institute Registry (22). In particular, the rates of procedure-related death (0% to 4%), systemic embolism (2% to 4%) and moderate increases in mitral regurgitation (30% to 40%) were almost identical, although the rate of cardiac tamponade appeared to be somewhat higher in our multicenter study (6% to 7% versus 1% to 2%). Cardiac perforation occurred in nine patients, and resulted in tamponade in seven patients. Emergency surgery was required in four of these patients, and two subsequently died, underlining the need to perform this procedure only in hospitals with facilities for cardiac surgery. Whether formal surgical backup should be required is an individual institutional decision that depends on the availability of operating rooms and the preferences of the cardiology and cardiac surgical staff.

Is there a learning curve for the procedure? Although we believe that operator experience is important in the performance of mitral valvuloplasty and that training in transseptal catheterization can reduce the incidence of cardiac perforation, we were unable to demonstrate a lower incidence of this and other complications in the centers with greater experience. There are several possible reasons why such a "learning curve" could not be demonstrated from registry data. First, the baseline level of operator experience with transseptal catheterization and valvuloplasty differed at each hospital. In some hospitals, the primary operator had received fellowship training in valvuloplasty; at other institu-

tions, the primary operator's training consisted only of observing one or two procedures at a demonstration course. Second, several hospitals "imported" experienced operators to assist in the performance of some or all of their procedures. Third, each center may learn from problems that are encountered at a different rate. Finally, the number of procedures necessary to lower the rate of complications may be greater than the number performed at even our most experienced center. Thus, if a learning curve in the performance of mitral valvuloplasty exists, it may be best demonstrated by comparing the early and late experience in a single center, rather than comparing small differences in the multiple centers of a registry.

Postvalvuloplasty regurgitation. Moderate and severe increases in mitral regurgitation of ≥2 angiographic grades occurred in 13% of patients, a rate similar to that found in other studies (23). Although the development of increased regurgitation was weakly correlated with balloon size, it is likely that other factors also contribute to its occurrence. One recent report (3) suggests that a posterior mitral leaflet tear may lead to severe mitral regurgitation in some patients with a calcified valve and extensive subvalvular disease. The majority of patients developing moderate grades of mitral regurgitation can be managed medically; only 1 of 15 patients in this study required mitral valve replacement for regurgitation during the 14.6 month follow-up period.

Atrial septal defect. The size of atrial septal defect was estimated by measuring the intracardiac left to right shunt after valvuloplasty (24). Our results demonstrating a measurable shunt in 18% of patients and a pulmonary to systemic flow ratio >1.3 in 7% of patients are similar to the previously reported rates of 20% (12) and 8.5% (3), respectively. Although a retrograde valvuloplasty technique that does not require dilation of the interatrial septum can reduce the incidence of shunts (18,19), the majority of these septal defects appear to close during short-term follow-up (12).

Follow-up. Clinical follow-up was obtained in all patients a mean of 14.6 months after valvuloplasty and revealed excellent symptomatic improvement, as previously reported by other investigators (3,12,16). Clinical evidence of restenosis developed in 10 (16%) of the 63 patients undergoing follow-up evaluation. Included in this group were nine patients who developed recurrent symptoms and one patient who died in part because of recurrent congestive heart failure. With multivariate analysis, the occurrence of restenosis could not be predicted by any pre- or postvalvuloplasty hemodynamic variable, the change in valve area or balloon size used during the procedure.

It is possible that the rate of restenosis based on hemodynamic or echocardiographic valve assessment may differ from the rate assessed by other means. However, Palacios et al. (12) obtained follow-up catheterization or echocardiographic data in 71 patients a mean of 13 months after valvuloplasty and demonstrated a loss of ≥50% of the initial gain in mitral valve area in a similar proportion of patients (18%). Furthermore, the restenosis rate was substantially higher in patients with a high echocardiographic score for leaflet thickening or immobility, valvular calcification or subvalvular thickening (42% versus 4%) (12).

Clinical implications. In this report, we have demonstrated that hemodynamic and clinical improvement can be obtained in the majority of adult patients with acquired mitral stenosis treated with mitral valvuloplasty in multiple centers. However, suboptimal results and major complications occurred in a significant number of patients. For this reason, we believe that mitral valvuloplasty should be performed only in centers with facilities for cardiac surgery and by operators experienced in transseptal catheterization techniques.

Finally, we believe that despite the early success of mitral valvuloplasty, it should remain an investigational technique at the current time. Surgical commissurotomy is a highly successful technique with a long record of experience (25), whereas the long-term outcome of balloon valvuloplasty is not yet known and the rate of certain complications may be higher. In addition, the criteria for optimal patient selection for balloon mitral valvuloplasty are still evolving (12) and technical aspects of the procedure are changing.

Appendix

Participating hospitals in the M-Heart Balloon Valvuloplasty Registry are as follows:

Center 1) University of Pennsylvania, Philadelphia, Pennsylvania. *Principal Investigator:* Howard C. Herrmann, MD. *Coinvestigators:* William G. Kussmaul, MD, Warren K. Laskey, MD, John W. Hirshfeld, Jr., MD, Carol A. Davis, RN.

Center 2) Temple University, Philadelphia, Pennsylvania. *Principal Investigator:* J. Patrick Kleaveland, MD. *Coinvestigators:* Ezra Deutsch, MD, Steve Heilbrunn, MD.

Center 3) University of Florida, Gainesville, Florida. *Principal Investigators:* James A. Hill, MD, Carl J. Pepine, MD. *Coinvestigators:* Charles R. Lambert, MD, PhD, Eilleen Hanberg, RN.

Center 4) Medical College of Virginia, Richmond, Virginia. *Principal Investigators:* Michael Cowley, MD, George Vetrovec, MD. *Coinvestigator:* Kim Cook, RN.

Center 5) Thomas Jefferson University, Philadelphia, Pennsylvania. *Principal Investigator:* Sheldon Goldberg, MD. *Coinvestigators:* Andrew Zalewski, MD, Michael Savage, MD, Patricia Wilson, RN.

Center 6) South Miami Hospital, Miami, Florida. *Principal Investigator:* James R. Margolis, MD. *Coinvestigators:* Jose C. Martin, MD, Daniel Krauthamer, MD, Juan C. Garcia MD, G. T. Welcom, RN.

Center 7) Florida Hospital Medical Center, Orlando, Florida. *Principal Investigators:* Michael A. Nocero, Jr., MD, Hall B. Whitworth, MD. *Coinvestigators:* Andrew Taussig, MD, Susie Lee, RN.

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